510(k) Summary

MAY 18 2010

510(k) Summary –T-PAL Spacer	
Name of Firm:	Synthes Spine 1302 Wrights Lane East West Chester, PA 19380
510(k) Contact:	Heather Guerin, Ph.D., P.E. Regulatory Affairs Specialist Telephone: 610-719-5432 Facsimile: 610-719-5102 Email: guerin.heather@synthes.com
Date Prepared:	May 12, 2010
Trade Name(s):	Synthes T-PAL Spacer
Classification:	21 CFR 888.3080 – Spinal Intervertebral Body Fusion Device Class II (Special Controls) Orthopaedic and Rehabilitation Devices Panel (87) Product Code MAX (orthosis, spinal intervertebral fusion)
Predicates:	Synthes T-PAL Spacer is substantially equivalent to similar previously cleared predicate devices.
Device Description(s):	The **Synthes T-PAL Spacer** is a radiolucent interbody fusion device used in conjunction with supplemental fixation to provide structural stability in skeletally mature individuals following total or partial discectomy. The T-PAL Spacer is available in two footprints and a range of heights, and is angulated 5° to accommodate the lordotic curve (except for the smallest height of each footprint, which does not have a lordotic angle). Pyramidal teeth that assist in stabilization of the construct are located on the inferior and superior surfaces of the spacers. These teeth are oriented along a contour that follows the curve of the implant to assist in implantation. A bullet-nose design also facilitates self-distraction and ease of insertion. The open architecture of the devices allows them to be packed with autogenous bone graft material, *i.e.*, autograft.
Intended Use/ Indications for Use:	Synthes T-PAL Spacer is indicated for use in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1 whose condition requires the use of interbody fusion combined with supplemental fixation. The interior of the T-PAL Spacer should be packed with autogenous bone graft (i.e. autograft). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. *The T-PAL Spacer is intended to be used with Synthes supplemental fixation, e.g. TSLP, ATB, Antegra, Pangea, Synthes USS (including Matrix, USS Small Stature Click'X, Pangea, USS Polyaxial, USS Iliosacral, and ClampFix).
Comparison of	Synthes T-PAL Spacer is substantially equivalent to the predicate in

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the device to predicate device(s):	design, function, performance, material, and intended use.
Performance Date (Non-Clinical and/or Clinical):	*Non-Clinical Performance and Conclusions:* Based the below listed performance tests, Synthes has determined that the Synthes T-PAL Spacer is substantially equivalent to the predicate devices: • Static Axial Compression • Dynamic Axial Compression • Subsidence • Expulsion • Static Compression Shear *Clinical Performance and Conclusions:* Clinical data and conclusions were not needed for this device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MAY 18 2010

Synthes Spine
% Ms. Heather Guerin, Ph.D., P.E.
Regulatory Affairs Specialist
1302 Wrights Lane East
Wet Chester, Pennsylvania 19380

Re: K100089
Trade/Device Name: Synthes T-PAL Spacer
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: April 16, 2010
Received: April 19, 2010

Dear Dr. Guerin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Barbara Brechner for

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

T-PAL Spacer

SYNTHES® Spine

510(k) Number(s): K100089
(if known)

Device Name: Synthes T-PAL Spacer

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Prescription Use X (21 CFR 801 Subpart D) AND / OR Over-the-Counter Use (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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